



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Re: Therma Choice™ Uterine Ballon Therapy System  
Docket Nos.: 98E-0485 and 98E-0850

MAY 11 1999

98E-0485 MAY 12 P1:49

The Honorable Q. Todd Dickinson  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent Nos. 5,105,808, and 4,949,718, filed by Gynelab Products, Inc., under 35 U.S.C. § 156 *et seq.* We have reviewed the dates contained in the applications and have determined the regulatory review period for Therma Choice™ Uterine Ballon Therapy System, the medical device claimed by the patents.

The total length of the regulatory review period for Therma Choice™ Uterine Ballon Therapy System is 1,031 days. Of this time, 852 days occurred during the testing phase and 179 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: February 17, 1995.

The applicant claims that the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 30, 1994. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 17, 1995, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: June 17, 1997.

The applicant claims June 16, 1997, as the date the Premarket Approval Application (PMA) Therma Choice™ Uterine Ballon Therapy System 5,105] (PMA P970021) was initially submitted. However, FDA records indicate that PMA P970021 was submitted on June 17, 1997.

3. The date the application was approved: December 12, 1997.

FDA has verified the applicant's claim that PMA P970021 was approved on December 12, 1997.

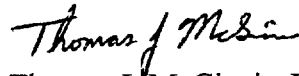
98E-0485

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This determination of the regulatory review period by FDA does not take into account the effective date of the patents, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, reading "Thomas J. McGinnis".

Thomas J. McGinnis, R.Ph.  
Deputy Associate Commissioner  
for Health Affairs

cc: Talivaldis Cepuritis  
Olson & Hierl, Ltd.  
36th Floor  
20 North Wacker Drive  
Chicago, IL 60606

DATE: MAY 11 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Therma Choice™ Uterine Ballon Therapy System

Docket Nos. 98E-0485 and 98E-0850, FRDTS# OC99129

Attached is a FR Notice for the medical device, Therma Choice™ Uterine Ballon Therapy System. This document has been internally reviewed and cleared by OHA.

Please note that Therma Choice™ Uterine Ballon Therapy System is a trademark. Therefore, the superscript "TM" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

8672 '99 MAY 12 P1:49

**Memorandum**

Date: **MAY 11 1999**

From: **Brian J. Malkin, Associate Director for Patents and Hearings  
Health Assessment Policy Staff (HFY-20)**

Subject: **Patent Term Restoration Application  
for **Therma Choice™ Uterine Ballon Therapy System****

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned medical device under Docket Numbers **98E-0485 and 98E-0850** stating that this particular patent is eligible for regulatory review. The Patent Numbers are **5,105,808 and 4,949,718**, respectively. Please place this recent correspondence in the appropriate files.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.